



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,088	02/02/2004	Chin-Chih Chiang	OEP2003-01	9267
26709	7590	05/29/2007		
SHIHONG NICOLAOU 4931 ARROYO LINDO AVE. SAN DIEGO, CA 92117			EXAMINER AHMED, HASAN SYED	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 05/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/770,088	Applicant(s) CHIANG, CHIN-CHIH	
	Examiner Hasan S. Ahmed	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20070515</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Receipt is acknowledged of applicant's request for continued examination, filed on 11 April 2007

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 April 2007 has been entered.

* * * * *

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground of rejection.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert, et. al. (U.S. 2003/0147926) in view of Oda, et. al. (U.S. 5,725,874).

Ebert, et. al. teach a topical gel formulation of oxybutynin as well as a method for treating bladder disorders using said topical gel (see above).

The disclosed formulation is comprised of 2.2 wt. % oxybutynin chloride salt; 58.8 wt. % of a short chain alcohol; and 2.0 wt % of a gelling agent (see example 10).

Although the Ebert, et. al. reference does not provide an example of a formulation with all excipients claimed by applicant, it teaches every excipient claimed, with the exception of diisopropanolamine:

- the short chain alcohols of instant claims 1 and 2, i.e., ethanol and isopropanol (see paragraph 0122);
- the gelling agents of instant claims 1, 3 and 4, i.e., CARBOPOL, CARBOMER and PEMULEN (see paragraph 0116);
- the permeation enhancers of instant claims 1 and 6, i.e., *inter alia*, isopropyl myristate (see paragraph 0134);
- the moisturizer of instant claims 1 and 9, i.e., propylene glycol (see paragraph 0127); and
- the method for treating bladder disorders of instant claim 10 (see paragraph 0017).

Art Unit: 1615

Ebert, et. al. explain that combining the disclosed agents into a topical gel formulation is beneficial because it mitigates the adverse drug effects associated with oxybutynin therapy (paragraphs 0006 and 0007).

The Ebert, et. al. reference differs from the instant application in that it does not disclose the diisopropanolamine of instant claim 1.

Oda, et. al. teach a gel formulation comprising oxybutynin (see col. 3, line 21) and diisopropanolamine (see col. 7, line 46).

Oda, et. al. explain that the diisopropanolamine is used as a pH neutralizing agent (see col. 7, line 46).

It would have been obvious to a person having ordinary skill in the art at the time of the invention to make a topical gel formulation of oxybutynin (comprising diisopropanolamine, a short chain alcohol, a gelling agent a permeation enhancer and a moisturizer) to treat bladder disorders, as taught by Ebert, et. al, in view of Oda, et. al. Motivation would come from mitigation of adverse drug effects associated with oxybutynin therapy, as taught by Ebert, et. al., as discussed above. Those of ordinary skill in the art would expect similar properties from the instant formulation, given the teachings of Ebert, et. al. and Oda, et. al.

★


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


HUMERA N. SHEIKH
PRIMARY EXAMINER

TC-1600